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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,185

04/02/2007

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

07/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,185	Applicant(s) FRANK ET AL.	
	Examiner ANISH GUPTA	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 10-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of n-propyl ether (PnP) as the elected species in the reply filed on 4/29/2010 is acknowledged. The traversal is on the ground(s) that the species related to a single inventive concept. This is not found persuasive because the single inventive concept argument does not take into account the burdensome search required to search each species. Claim 7 outlines numerous glycol ethers which would each require an independent search because of their distinct structure. Furthermore, the alcohols of claim 2 would require more of a separate search since they do not fall within the glycol ether class of compounds. Thus, there is a burdensome search to search all of the species claimed and the election is therefore proper.

The requirement is still deemed proper and is therefore made FINAL.

A search was conducted for the elected species and it was deemed to be free of the prior art. The search was extended to another species, 2-propanol, and prior art was found that anticipated the claimed invention. This prior art has been applied to the claims.

The prior art species read on claims 1-3, 8-9. Claims 4-7, 10-21 are withdrawn from consideration as corresponding to nonelected species. It is noted that claims 5 and 7 are withdrawn even though they contain the elected species PnP. These claims, however, also contain other nonelected species for which the search has not been extended. The MPEP states "If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, **will not be extended unnecessarily to cover all nonelected species.**" See MPEP 803.02. Since prior art was found on

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the species recited in claim 3, the search was not extended to the other species. For this reason claims drawn to the use of glycol ethers beyond PnP have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (US5304310).

The claims are drawn to a method of purifying proteins using 2-propanol.

The reference teaches a method of purifying Protein A-hirudin fusion protein from E.Coli expression (see col. 3). Specifically, the reference teaches that the starting material used was the precipitate from the precipitation of an E. coli cell disruption. It received inactive hirudin in the form of a fusion protein with the N-terminal region of protein A from Staphylococcus aureus. The protein portion of the fusion protein in the total protein was about 40%. Besides extraneous proteins, the precipitate contained large amounts of cell and fermentation constituents. This precipitate then was mixed with water and the pH was adjusted to 5 (see col. 3, lines 35-36). The precipitate was then subject to i-propanol at pH 5 and the insoluble material was removed by centrifugation (see col. 3, lines 39-42). Note that the reference teaches 2-propanol, the species of claim 3, and teaches the addition of the propanol to the water resulted in one phase containing the protein which was separated from the solids. This meets the limitation of step (a) and (b) in the claimed method. The reference further teaches that the supernatant containing the water miscible

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alcohol was then subject to sodium chloride to form separate organic and aqueous phase (see col. 3, lines 42-47). This teaching meets the limitation of claim 8. The reference teaches that the protein was in the aqueous phase and was subsequently recovered (see col. 3 and claims).

The reference anticipates the claimed invention.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654